

FORM PTO-1449/A and B (modified PTO/SB/08)

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

APPLICATION NO.: 10/613,749

ATTY. DOCKET NO.: C1037.70041US00

FILING DATE: July 3, 2003

CONFIRMATION NO.: 6452

APPLICANT: Arthur M. Krieg et al.

GROUP ART UNIT: 1645

EXAMINER: Nita M. Minnifield

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U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A246	4,806,463		Goodchild et al.	02-21-1989
	A247	5,004,810		Draper	04-02-1991
	A248	5,166,195		Ecker	11-24-1992
	A249	5,194,428		Agrawal et al.	03-16-1993
	A250	5,264,423		Cohen et al.	11-23-1993
	A251	5,276,019		Cohen et al.	01-04-1994
	A252	5,416,203		Letsinger	05-16-1995
	A253	6,749,856	B1	Berzofsky et al.	06-15-2004
	A254	7,303,881	B2	Huang et al.	12-04-2007
	A255	7,354,711	B2	Macfarlane	04-08-2008
	A256	7,402,572	B2	Krieg et al.	07-22-2008
	A257	7,410,975	B2	Lipford et al.	08-12-2008
	A258	2002-0142977	A1	Raz et al.	10-03-2002
	A259	2002-0151518	A1	Agrawal et al	10-17-2002
	A260	2002-0168340	A1	Agrawal	11-14-2002
	A261	2003-0032443	A1	Johnson et al.	02-13-2003
	A262	2003-0129605	A1	Yu et al.	07-10-2003
	A263	2003-0176389	A1	Raz et al.	07-10-2003
	A264	2003-0212029	A1	Agrawal et al.	11-13-2003
	A265	2003-0225016	A1	Fearon et al.	12-04-2003
	A266	2003-0232443	A1	Bennett et al.	12-18-2003
	A267	2004-0006010	A1	Carson et al.	01-08-2004
	A268	2008-0113929	A1	Lipford et al.	05-15-2008
	A269	2008-0226649	A1	Schetter et al.	09-18-2008

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B38	EP	1 187 629	A2	Smithkline Beecham Biologicals, S.A.	10-26-2000	
	B39	WO	95/03407	A2	Gen-Probe Incorporated	02-02-1995	

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				GROUP ART UNIT: 1645		EXAMINER: Nita M. Minnifield			
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	B40	WO	99/63975	A2	Biognostik Gesellschaft Fur Biomolekular Diagnostik MBH	12-16-1999	
	B41	WO	2004/012669	A2	The Government of the United States	02-12-2004	
	B42	WO	2008/030455	A2	Coley Pharmaceutical Group, Inc.	03-13-2008	
	B43	WO	2008/033432	A2	Coley Pharmaceutical Group, Inc.	03-20-2008	
	B44	WO	2008/039538	A2	Coley Pharmaceutical Group, Inc.	04-03-2008	
	B45	WO	2008/068638	A2	Coley Pharmaceutical GMBH	06-12-2008	

OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C267	[No Author Listed] CPG10101 HCV Toll-Receptor 9 Antagonist Phase II Study Results. 57 th Annual Meeting of the American Association for the Study of Liver Diseases. October 27-31, 2006. Boston, MA. 9 pages.	
	C268	[No Author Listed] Mechanisms of Microbial Diseases, Third Edition. Schaechter et al., editors. Lippencott, Williams & Wilkins, 1999. p.xv-xvi.	
	C269	AHLUWALIA et al., Immunostimulatory profiles from two classes of CpG ODN administered subcutaneously to healthy subjects. ICI FOCIS 2004. Poster.	
	C270	CONNELL et al., Anti-tumor activity of a CpG-containing oligodeoxynucleotide (ODN) in athymic mice. American Assn Cancer Reseach. March 1999;40:abstract 1982.	
	C271	DENG et al., CpG oligodeoxynucleotides stimulate protective innate immunity against pulmonary Klebsiella infection. J Immunol. 2004 Oct 15;173(8):5148-55.	
	C272	ECKSTEIN et al., Phosphorothioation of DNA in bacteria. Nat Chem Biol. 2007 Nov;3(11):689-90.	
	C273	DIWAN et al., Enhancement of immune responses by co-delivery of a CpG oligodeoxynucleotide and tetanus toxoid in biodegradable nanospheres. J Control Release. 2002 Dec 13;85(1-3):247-62.	
	C274	GOLDBERG et al., Beyond danger: unmethylated CpG dinucleotides and the immunopathogenesis of disease. Immunol Lett. 2000 Jul 3;73(1):13-8.	
	C275	HARANDI et al., A protective role of locally administered immunostimulatory CpG oligodeoxynucleotide in a mouse model of genital herpes infection. J Virol. 2003 Jan;77(2):953-62.	
	C276	HARTMANN et al., Rational design of new CpG oligonucleotides that combine B cell activation with high IFN-alpha induction in plasmacytoid dendritic cells. Eur J Immunol. 2003 Jun;33(6):1633-41.	
	C277	HARTMANN et al., Identification and functional analysis of tumor-infiltrating plasmacytoid dendritic cells in head and neck cancer. Cancer Res. 2003 Oct 1;63(19):6478-87.	
	C278	HORNER et al., Immunostimulatory DNA is a potent mucosal adjuvant. Cell Immunol. 1998 Nov 25;190(1):77-82.	
	C279	ISHII et al., Antitumor therapy with bacterial DNA and toxin: complete regression of established tumor induced by liposomal CpG oligodeoxynucleotides plus interleukin-13 cytotoxin. Clin Cancer Res. 2003 Dec 15;9(17):6516-22.	
	C280	JIANG et al., Synthetic vaccines: the role of adjuvants in immune targeting. Curr Med Chem. 2003 Aug;10(15):1423-39.	

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Sheet	3	of	4		

	C281	KANDIMALLA et al., Secondary structures in CpG oligonucleotides affect immunostimulatory activity. Biochem Biophys Res Commun. 2003 Jul 11;306(4):948-53.	
	C282	KIM et al., TLR9 Agonist Immunomodulator Treatment of Cutaneous T-cell Lymphomas (CTCL) with CPG7909. Blood. 2004 Nov16;104(11):Abstract #743.	
	C283	LEE et al., Effects of a hexameric deoxyriboguanosine run conjugation into CpG oligodeoxynucleotides on their immunostimulatory potentials. J Immunol. 2000 Oct 1;165(7):3631-9.	
	C284	LI et al., Effective induction of CD8+ T-cell response using CpG oligodeoxynucleotides and HER-2/neu-derived peptide co-encapsulated in liposomes. Vaccine. 2003 Jul 4;21(23):3319-29.	
	C285	MARSHALL et al., Identification of a novel CpG DNA class and motif that optimally stimulate B cell and plasmacytoid dendritic cell functions. J Leukoc Biol. 2003 Jun;73(6):781-92.	
	C286	NORMAN et al., Liposome-mediated, nonviral gene transfer induces a systemic inflammatory response which can exacerbate pre-existing inflammation. Gene Ther. 2000;7:1425-30.	
	C287	READETT et al., PF-3512676 (CPG7909) a toll-like receptor 9 agonist – status of development for Non-small cell lung cancer (NSCLC). Abstract PD3-1-6. Pfizer. 24 Aug. 2007. Poster.	
	C288	RUDGINSKY et al., Antitumor activity of cationic lipid complexed with immunostimulatory DNA. Mol Ther. 2001 Oct;4(4):347-55.	
	C289	SCHELLER et al., CpG oligodeoxynucleotides activate HIV replication in latently infected human T cells. J Biol Chem. 2004 May 21;279(21):21897-902. Epub 2004 Mar 11.	
	C290	SCHEULE, The role of CpG motifs in immunostimulation and gene therapy. Adv Drug Deliv Rev. 2000 Nov 15;44(2-3):119-34.	
	C291	SCHWARZ et al., Role of Toll-like receptors in costimulating cytotoxic T cell responses. Eur J Immunol. 2003 Jun;33(6):1465-70.	
	C292	SFONDRINI et al., Prevention of spontaneous mammary adenocarcinoma in HER-2/neu transgenic mice by foreign DNA. FASEB J. 2002 Nov;16(13):1749-54.	
	C293	SHALABY, Development of oral vaccines to stimulate mucosal and systemic immunity: barriers and novel strategies. Clin Immunol Immunopathol. 1995 Feb;74(2):127-34.	
	C294	STOREY et al., Anti-sense phosphorothioate oligonucleotides have both specific and non-specific effects on cells containing human papillomavirus type 16. Nucleic Acids Res. 1991 Aug 11;19(15):4109-14.	
	C295	VOLLMER et al., Impact of modifications of heterocyclic bases in CpG dinucleotides on their immune-modulatory activity. J Leukoc Biol. 2004 Sep;76(3):585-93. Epub 2004 Jun 24.	
	C296	VOLLMER, TLR9 in health and disease. Int Rev Immunol. 2006 May-Aug;25(3-4):155-81.	
	C297	WANG et al., Phosphorothioation of DNA in bacteria by dnd genes. Nat Chem Biol. 2007 Nov;3(11):709-10. Epub 2007 Oct 14. Supplementary information, 12 pages.	
	C298	WHITMORE et al., Systemic administration of LPD prepared with CpG oligonucleotides inhibits the growth of established pulmonary metastases by stimulating innate and acquired antitumor immune responses. Canc Immun Immunother. 2001;50:503-14.	
	C299	WHITMORE et al., LPD lipopolyplex initiates a potent cytokine response and inhibits tumor growth. Gene Ther. 1999;6:1867-75.	
	C300	YAMADA et al., Effect of suppressive DNA on CpG-induced immune activation. J Immunol. 2002 Nov 15;169(10):5590-4.	
	C301	YU et al., Potent CpG oligonucleotides containing phosphodiester linkages: in vitro and in vivo immunostimulatory properties. Biochem Biophys Res Commun. 2002 Sep 13;297(1):83-90.	

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Sheet	4	of	4		

	C302	ZHANG et al., Antisense oligonucleotide inhibition of hepatitis C virus (HCV) gene expression in livers of mice infected with an HCV-vaccinia virus recombinant. Antimicrob Agents Chemother: 1999 Feb;43(2):347-53.	
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[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]

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